

全例調査をどう考えるか**

—産より(1)：アバスチン® 全例調査と適正使用について—

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**Post-Marketing Surveillance on all Patients Treated
with Avastin® and Appropriate Use**

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Summary

Avastin (an anti-VEGF drug : bevacizumab) was approved in April 2007 in Japan for advanced colorectal cancer. Because the number of patients in Japanese clinical trials has been extremely limited, the authorities requested that a survey be conducted on all patients (post-marketing surveillance; PMS) for a certain period after launch as a post-approval commitment.

We conducted PMS, taking into account available medical facilities, doctors, and distribution management, with provision of information by booklet and website, preregistration of scheduled patients, and detailed monitoring of side effects in all registered patients. An external committee was established for oversight.

Adverse drug responses (ADRs) were reported in 58.9% of patients and serious ADRs were reported in 14.1% of patients. Major ADRs for bevacizumab were hypertension (13.0% of patients), hemorrhage (11.3% (epistaxis 7.3%)), and proteinuria (4.1%). The majority of ADRs were not serious; overall, the incidence of serious ADRs was low. No major difference was found between the trends of ADR incidence in all patients in the PMS and in overseas observational studies. (46th JSCO)

Trends of ADR incidence remained constant after launch. We think that PMS of all patients contributes to appropriate drug use and safety.

Key words

Avastin, Bevacizumab, VEGF, Post-Marketing surveillance, PMS, Safety measures